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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,467	02/21/2003	Anette A Herscovics	701826-052310	6366

7590

12/01/2004

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,467

Applicant(s)

HERSCOVICS ET AL.

Examiner

Kagnew H Gebreyesus

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Priority:

Claims 9 and 10 are not disclosed in the provisional application therefore the benefit of the earlier filing date i.e. 06/28/99 will not apply to groups that contain these claims.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claim 1 is drawn to a human alpha 1,2-mannosidase enzyme for specifically converting Man9GlcNAc to Man8GlcNAc isomer B in degradation mechanism of misfolded proteins, wherein said enzyme has the characteristics of an enzyme encoded by a cDNA sequence set forth in SEQ ID NO: 18.
- II. Claim 2 and 3 in part and claim 4 are drawn to an antagonist of alpha 1,2-mannosidase enzyme for inhibiting the enzyme.
- III. Claims 5-8 are drawn to a method for treating a genetic disease causing a misfolding of the proteins in a patient, which comprises administering an antagonist of alpha 1,2-mannosidase enzyme for transiently inhibiting the enzyme, thereby preventing degradation of misfolded proteins.
- IV. Claim 2 and 3 in part are drawn to an agonist of alpha 1,2-mannosidase enzyme for activating the enzyme.

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- V. Claims 9 and 10 are drawn to the use of a mutant alpha 1,2-manosidase enzyme to produce altered recombinant glycoproteins with improved uptake to treat genetic disease characterized by formation of misfolded glycoproteins resulting in their degradation and/or improper localization.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There are no technical features linking all the five (I-V) groups. The use of an antagonist to inhibit a class I alpha 1,2-manosidase enzyme in order to treat a genetic disorder related to protein misfolding and degradation is the only technical feature linking groups II and III. However antagonists and of class I alpha 1,2-manosidase enzymes are known in the art. Bishoff et al., (JBC 1986, vol. 261, No. 10 pp 4766-4774) describe the use of 1-Deoxymannojirimycin to evaluate the role of various alpha mannosidases in oligosaccharide processing in intact cells. As such the only technical feature of Groups II and III is not special as defined by PCT rule 13.2 as it does not define a contribution over the prior art.

Applicants have not disclosed the utility for the agonist in relation to the treatment of a genetic disorder and therefor the claimed invention in Group I-III, and V are technically unrelated to the inventions of group IV. In addition the mutant alpha 1,2-manosidase of group V used for treating the genetic disorder has a different mode of operation than the mode of operation of the inventions of Group I-IV. Therefor the invention of group V is regarded as an independent invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

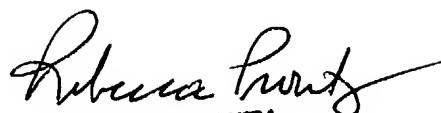
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagne Gebreyesus Ph.D
AU 1652


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